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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,244	07/23/2003	Nicholas V. Perricone	00961-P0213A	3183
24126	7590	07/22/2005	EXAMINER	
ST. ONGE STEWARD JOHNSTON & REENS, LLC			OH, SIMON J	
986 BEDFORD STREET			ART UNIT	
STAMFORD, CT 06905-5619			PAPER NUMBER	

1618

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,244

Applicant(s)

PERRICONE, NICHOLAS V.

Examiner

Simon J. Oh

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1618

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 09 May 2005.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 10, 14-18, 21, and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is hereby withdrawn.

The rejection of Claim 12 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence

Art Unit: 1618

of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides for topical compositions comprising an effective amount of an allithiamine, such as benfotiamine. Methods for treatment and prevention of aging and/or other skin conditions are also recited.

(2) The state of the prior art

The art has taught that allithiamines, such as benfotiamine, are useful as a component in topical compositions. However, the art is silent with respect to the use of this component in the actual prevention of aging or glycation.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

In the view of the examiner, the art has set forth that protein glycation cannot be completely prevented in a predictable manner.

(5) The breadth of the claims

The claims are very broad. The instantly claimed methods recite that the prevention of the formation of glycated proteins is entirely attributable to the administration of an allithiamine, such as benfotiamine.

(6) The amount of direction or guidance presented

Art Unit: 1618

The specification does not present any data that conclusively shows that glycation can be entirely prevented due to the administration of a composition comprising an allithiamine, such as benfotiamine. The instant disclosure states in Paragraph 0004 that benfotiamine is believed to prevent sugars in cells from combining with proteins to form advanced glycation endproducts. This statement seems to suggest that the specific pharmacokinetic behavior of benfotiamine is not entirely understood.

(7) The presence or absence of working examples

No working examples have been provided which show that the instantly claimed invention prevents glycation.

(8) The quantity of experimentation necessary

In the view of the examiner, one of ordinary skill in the art would be burdened with undue “painstaking experimentation study” to determine conclusively that the complete prevention of glycation can be achieved in a manner that is directly attributable to the administration of an allithiamine, such as benfotiamine.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Runge *et al.* and Woerwag *et al.* is maintained.

Response to Arguments

Applicant's arguments filed 09 May 2005 have been fully considered but they are not persuasive.

The enablement rejection of Claim 12, under 35 U.S.C. 112, first paragraph, is maintained, since in the examiner's view, the instant specification does not enable one of ordinary skill in the art to reliably prevent damage or the formation of glycated proteins. An enablement rejection has now been made for Claim 13, also for the reason that the instant specification does not reasonably provide for the prevention of the formation of glycated proteins. While the applicant may not agree with the examiner's interpretation of the instant claims or the instant specification, the applicant's response raises two questions. First, how can a condition be truly prevented if it not prevented entirely? Secondly, how can the prevention of such a condition be observed and measured, especially since it is suggested by the applicant's own specification that the specific pharmacokinetic behavior of the active ingredient that is administered is not entirely understood? In the view of the examiner, the applicant has not, to this point, given satisfactory answers to these questions.

In response to applicant's argument that the references fail to make obvious the instantly claimed invention, it is the position of the examiner that the applicant has not shown a patentable distinction between what is being claimed and what has been taught by the prior art. The applicant has stated that the presence of glycated proteins cause inflammation and irritation. Although the applicant argues that the symptoms of shingles are different from the symptoms of glycated proteins, the examiner does not a patentable distinction between inflammation and irritation, as attributed to the presence of glycated proteins, and rashes and itchiness, as attributed to shingles. The examiner also maintains that rheumatic disorders also have symptoms of inflammation and irritation.

Art Unit: 1618

Furthermore, the examiner notes that there is an overlap in the patient populations between those that would likely be treated by the instantly claimed methods and those of the prior art suffering from rheumatic disorders and shingles, who are more likely to be middle-aged or elderly. As the prior art has already broadly disclosed that topical benfotiamine compositions are useful for the treatment of skin conditions, and given the overlap of patient populations, it is the position of the examiner that the methods of the prior art make obvious the instantly claimed invention. Thus, all pending claims remain rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit 1618

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600